U.S. Patent Application No. 09/457,771 Amendment and Response to Office Action Page 6

REMARKS

The present application is directed to compositions and methods involving therapeutic delivery compounds. The compounds are particularly suited for the effective delivery of genetic matter and other compounds to the interior of cells.

Following entry of this amendment, Claims 1, 22-23, 25, 27-30 and 37-38 will be pending. Claims 2-21, 24, 26, 31-36 and 39-42 have been cancelled without prejudice. Claims 1, 22, 23, 25, 28, 37, and 38 are currently amended. No new matter is added and support for the amendments is found throughout the specification.

Claim rejections under 35 U.S.C. § 112, second paragraph

In the Office Action mailed October 18, 2005, the Examiner rejected Claims 1, 22, 23, 25, 27-31, 37 and 38-40 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that the amendments to the claims over the rejection.

Claims 1, 22, 23, 25 and 37 have been amended, as suggested by the Examiner, to clarify that the composition and methods define a combined molecular weight of both hydrophilic regions of the block copolymer.

Claims with Markush groups have been amended, as suggested by the Examiner, to follow a list of species with a phrase beginning with the word "and" rather than the word "or".

Claims 28 has been amended to clarify that the nucleic acid molecules encode an antisense oligonucleotide.

Claims 31 and 39-40 have been cancelled without prejudice and render the Examiner's rejection moot. Accordingly, applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

Claim rejections under 35 U.S.C. § 102

In the Office Action mailed October 18, 2005, the Examiner rejected Claim 23 as anticipated by Allison et al. (U.S. 5,376,369; hereinafter "Allison et al.") under 35 U.S.C. §102(e).

9143000.2

04/18/2006 12:22 4048156118 KILPATRICK_STOCKTON PAGE 11/13

U.S. Patent Application No. 09/457,771 Amendment and Response to Office Action Page 7

Applicants respectfully submit that Allison et al. fail to teach administration of whole viruses and therefore do not anticipate supplying a normal copy of a defective gene. Example 9 states that "the ovalbumin vaccine of Example 4 was prepared as described in Composition 4, Example 1, but using the following antigens in place of ovalbumin (Column 23, lines 24-26). The term "antigen" is defined on column 7, lines 5-13 as a "protein or glycoprotein, lipoprotein, saccharide, poly-saccharide or lipopolysaccharide." Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

The Examiner rejected Claim 23 as anticipated under 35 U.S.C. §102(e) by Wasmoen et al. (U.S. 5,656,275; hereinafter "Wasmoen et al."). Applicants respectfully submit that amendments to the claims overcome the rejection.

Claim 23 has been amended to require that the gene supplied be a normal copy of one of the animal's defective genes and not simply a copy of an unrelated gene from another organism. Support for the amendment is found on pages 22-23, lines 25-4. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(e).

Claim rejections under 35 U.S.C. § 103

In the October 18, 2005 Office Action, the Examiner rejected Claims 25, 27, 28 and 30 as unpatentable under 35 U.S.C. §103(a) over Lee et al. (U.S. 5,470,568; hereinafter "Lee et al."). Applicants respectfully submit that amendments to the claims overcome the rejection.

Claim 25 has been amended to clarify that the nonionic block copolymer facilitates entry of the molecule into a cell. The ability of these copolymers to facilitate entry of DNA into cells without an additional permeabilization step or delivery agent represents an unexpected result not previously appreciated by those skilled in the art (page 9, lines 5-25). Furthermore, Lee et al. teach away from the use of nonionic copolymers as a means for facilitating entry of DNA into cells by requiring an additional permeabilization step prior to contacting the cell with the DNA, by teaching that the polymer can be applied after the introduction of DNA into the cell, and by stating that the polymers function to stabilize or reduce the permeability of the cell membrane

04/18/2006 12:22 4048156118 KILPATRICK_STOCKTON PAGE 12/13

U.S. Patent Application No. 09/457,771 Amendment and Response to Office Action Page 8

(column 10, lines 43-50 and claims 20-22). Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

The Examiner rejected Claims 22 and 23 as unpatentable under 35 U.S.C. §103(a) over Lee et al. in view of Felgner et al. U.S. 5,459,127 (hereinafter "Felgner"). Applicants respectfully submit that amendments to the claims overcome the rejections.

Claims 22 and 23 have been amended to clarify that the nonionic block copolymer facilitates entry of the molecule into a cell." As mentioned above in regards to the rejection of Claim 25, Lee et al. fail to teach or suggest the ability of nonionic copolymers to facilitate entry of DNA into cells without an additional permeabilization step or delivery agent. Felgner teaches the ability of cationic lipids to mediate delivery of DNA into cells. The deficiencies of Lee et al. are not satisfied by Felgner because Felgner also fails to teach or suggest the ability of nonionic block copolymers to facilitate entry of DNA into cells without an additional permeabilization step or delivery agent. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed October 18, 2005. For at least the reasons given above, applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

9143006.2

U.S. Patent Application No. 09/457,771 Amendment and Response to Office Action Page 9

The Examiner is invited and encouraged to contact the undersigned attorney of record at 404-745-2473, or the telephone number listed below, if the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment or there are any other issues that can be resolved by telephone interview.

Respectfully submitted,

Jamie L. Greene. Reg. No. 32,467

KILPATRICK STOCKTON LLP 1100 Peachtree Street, Suite 2800 Atlanta, Georgia 30309 Telephone: 404-815-6500

Attorney Docket No. 19720-0624 (42896-216422)